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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/337,619	06/21/99	KREIG	A C1039/7021HC

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EXAMINER

MARTINELL, J

ART UNIT PAPER NUMBER

1633

DATE MAILED: 10/03/00

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/337,619

Applicant(s)
Kreig et al

Examiner
James Martinell

Group Art Unit
1633



☒ Responsive to communication(s) filed on Jul 27, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1 and 42-75 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1 and 42-75 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

The references crossed out on the copy of form PTO-1449 were not considered because copies of these references could not be found in the parent files. Applicants may submit copies of these articles for consideration in response to this Office action without the submission of any fee for such consideration.

In view of the papers filed July 27, 2000, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by the addition of Dr. George Weiner.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing

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receipt, and correction of the file jacket and PTO PALM data to reflect the inventorship as corrected.

The disclosure is objected to because of the following informalities.

- (a) On page 38 the last line is illegible. It follows the line beginning with "1842".
- (b) In claim 72, "modificati0on" is a typographical error.
- (c) On page 47, the fourth line after the table is not completely legible.

Appropriate correction is required.

The following is a quotation of the first paragraph of 35

U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35

U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 42-75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague, indefinite, incomplete, inaccurate, and misdescriptive.

(a) The recitation of "increasing the responsiveness"

(claim 42) is vague, indefinite, and incomplete.

First, the metes and bounds of the term

"responsiveness" are not known within the context of the claim. Second, the phrase is a relative one with on frame of reference given.

(b) The recitation of "including at least the following

formula" (claim 42, 66, and 71) is vague, indefinite, misdescriptive, and inaccurate. A formula for a

compound is considered to be the complete structure of a molecule of that compound. If what is referred to in

the claim is a subsequence of a possibly larger sequence, the claim should be amended to refer to the "formula" as a sequence or a subsequence.

- (c) The recitation of "phosphate backbone modification of the 5' end of the nucleic acid" (claim 57) is misdescriptive and inaccurate because the backbone of a nucleic acid is between bases, not at the end of the molecule.
- (d) The recitation of "phosphate backbone modification of the 3' end of the nucleic acid" (claim 58) is misdescriptive and inaccurate because the backbone of a nucleic acid is between bases, not at the end of the molecule.
- (e) The recitation of "enhancing recovery of bone marrow" (claim 66) is vague and indefinite because the phrase is a relative one with no frame of reference given.

Claims 42-75 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described

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in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The instant application gives no data relevant to the use of the nucleic acids mentioned in the claims in any in vivo method to control or affect any of the conditions mentioned in the claims. One of skill in the art would be compelled to perform undue experimentation in order to practice the claimed invention because of the large number of variables connected with the use of such nucleic acids. For example, the instant application does not give guidance as to the type of administration, the times or frequencies of administration, or the dosages required to obtain the desired effects.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple

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assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 25, 32, 33, 40, and 48 of copending Application No. 08/738,652. Although the conflicting claims are not identical, they are not patentably distinct from each other

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because the oligonucleotides of Serial No. 08/738,652 are embraced by the oligonucleotides of Claim 1 of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of copending Application No. 09/337,893. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Yamamoto et al (J. Immunol. 148: 4072 (1992)). The oligonucleotides disclosed in the reference are embraced by the claim. For example, see the Abstract and the Results section.

Certain papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1633 at (703) 308-4242. The faxing of such papers must conform with the rules published in the Official Gazette, 1156 OG 61 (November 16, 1993).

Any inquiry concerning this communication should be directed to J. Martinell at telephone number (703) 308-0296.


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SENIOR LEVEL EXAMINER